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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,544	12/14/2005	Breda Mary Cullen	101713-5033	6443

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MORGAN, LEWIS & BOCKIUS LLP
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EXAMINER

WESTERBERG, NISSA M

ART UNIT	PAPER NUMBER
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1618

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,544	Applicant(s) CULLEN ET AL.	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5 - 13, 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' arguments, filed October 22, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 11 – 13 and 20 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 18 of copending Application No. 10/579897. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 22, 2009 and those set forth below.

Applicant requests that this rejection be held in abeyance. Therefore, this rejection is maintained for the reasons of record.

4. Claims 1 – 3 and 20 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, and 13 of copending Application No. 11/608553 in view of Partain (EP 0368253). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed October 1, 2007, May 13, 2008 and May 22, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that the combination of references does not yield a wound dressing material dyed with an antioxidant dyestuff wherein the dyestuff is bound to the surface of the bioabsorbable substrate, allowing for sustained release of effective amounts of the antioxidant dyestuff. Partain does not teach a solid material being surface-treated while in the solid state with a dye to bind the dye. Partain does not provide any teaching, suggestion or motivation to prepare such a material

These arguments are unpersuasive. The instant claims and the claims of US'553 are drawn to a composition and the patentability of the composition is based on the composition itself "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) **MPEP 2113**. Applicants have not presented any evidence that the compositions obtained when the dye and bioabsorbable substrate are combined in the liquid state results in a product that is different and non-obvious over the product obtained by the process of Partain.

Also, an explicit teaching, suggestion or motivation in the art is not required to establish obviousness. As set forth on p 7 – 8 of the October 1, 2007 Office Action, one of ordinary skill in the art would be motivated to add an antioxidant dyestuff to the

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oxidized cellulose composition recited in the claims of US'553 due to the antioxidant nature of the acridine dyestuffs which act as antiseptic agents, as taught by Partain.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 5, 6 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al. (EP 0368253) in view of Rosenthal et al. (US 5,565,210). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed May 13, 2008 and May 22, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that there is disclosure by Partain or Rosenthal of dyeing a bioabsorbable wound dressing material with an antioxidant dye. The term "dyed" in the instant claims refers to a solid material that has been surface-treated while in the solid state with a dye to bind the dye, while Partain discloses a delivery system that contains actives that can be topically applied, including acridine dyes. The Examiner has incorrectly equated the teaching of addition of a dyestuff to an aqueous solution for preparation of a final product with Applicants' presently claimed invention. Neither reference teaches a "dyed" composition or that any of the materials in the mixture are covalently modified by a dyestuff. In fact, Partain teaches the chitosan materials are "salts" which are ionic and not covalent preparations. Partain does not teach covalent modification of the composition with a dyestuff and does not teach or suggest the use of cellulose of any type to prepare any type of composition. Rosenthal does not cure these deficiencies. While Rosenthal may teach the use of an oxidized cellulose to make a bioabsorbable material, Rosenthal does not teach dyeing of a cellulose using a dyestuff. There is no teaching or suggestion in either

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reference to use the compositions of Rosenthal to prepare compositions according to Partain. Assuming, *arguendo*, that a skilled artisan would think to use a saccharide other than chitosan, there is still no teaching in either reference as to how or why the skilled artisan would dye a composition as taught by the instant claims.

These arguments are unpersuasive. The instant claims are drawn to a composition and the patentability of the composition is based on the composition itself "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) **MPEP 2113**. Applicants have not presented any evidence that the compositions obtained when the dye and bioabsorbable substrate are combined in the liquid state that the product is different and non-obvious over the product obtained by the process of Partain.

Also, the claims and definition presented in the specification for "dyed" does not require a covalent attachment between the substrate and the dye molecule. In fact, the Examiner is unaware that dyeing of any substrate requires a covalent interaction between the substrate, as such interactions would seem to make impossible the turning of a load of white laundry pink when a red item is mistakenly included in the load. Further discussion and/or evidence as to the covalent linkage between the antioxidant

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dyestuff and the solid bioabsorbable substrate is required. Applicants' arguments without factual support are mere allegations and are not found to be persuasive.

As to Partain not teaching oxidized cellulose materials, that omission is the reason this rejection is made in combination with Rosenthal, which does teach oxidized cellulose materials. As set forth on p 7 of the May 13, 2008 Office Action, oxidized cellulose is functionally equivalent to the chitosan materials taught by Partain, a fact appreciated by the teachings of Rosenthal. The substitution of one material known in the cited prior art to be functionally equivalent is sufficient to establish a *prima facie* case of obviousness. An explicit teaching, suggestion or motivation in the prior art documents themselves is not required to establish a *prima facie* case of obviousness.

9. Claims 1, 5 – 7, 13 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al. and Rosenthal et al. further in view of Fowler et al. (US 5,667,501). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed May 13, 2008 and May 22, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Fowler does not correct the deficiency, discussed above, of Partain and Rosenthal. Fowler does not teach a solid material that has been surface-treated while in a solid state with a dye to bind the dye or an oxidized cellulose having a covalently bond antioxidant dyestuff. Taken together these references do not provide any teaching, suggestion or motivation to arrive at the presently claimed invention and so would not have any expectation of success without the use of improper hindsight reasoning.

These arguments are unpersuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

As discussed in greater detail above, the claims as presented do not require covalent attachment of the antioxidant dyestuff to the bioabsorbable material. The references of Partain and Rosenthal are not deficient in regards to the independent claim, as discussed in greater detail above. Therefore, Fowler et al. is not required to cure these deficiencies. Applicants have not presented any arguments in regards to the teachings of Fowler as to the free radical activity and amount of dye present in the composition. Therefore, this rejection is maintained for the reasons of record.

10. Claims 1, 5 – 10 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al., Rosenthal et al. and Fowler et al. further in view of Nimrod et al. (WO 87/05517). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed May 13, 2008 and May 22, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Nimrod does not correct the deficiency, discussed above, of Partain, Rosenthal and Fowler. Nimrod does not teach a solid material that has been surface-treated while in a solid state with a dye to bind the dye or an oxidized cellulose having a covalently bond antioxidant dyestuff. Taken together these references do not provide any teaching, suggestion or motivation to arrive at the presently claimed invention and so would not have any expectation of success without the use of improper hindsight reasoning.

These arguments are unpersuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

As discussed in greater detail above, the claims as presented do not require covalent attachment of the antioxidant dyestuff to the bioabsorbable material. The references of Partain and Rosenthal are not deficient in regards to the independent claim, as discussed in greater detail above. Therefore, Nimrod et al. is not required to cure these deficiencies. Applicants have not presented any arguments in regards to the teachings of Nimrod regarding the inclusion of a silver salt in the composition. Therefore, this rejection is maintained for the reasons of record.

11. Claims 1, 5 – 12 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al., Rosenthal et al. and Fowler et al. further in view of Gibbins (US 6,355,858). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed May 13, 2008 and May 22, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Gibbins does not correct the deficiency, discussed above, of Partain, Rosenthal and Fowler. Gibbins does not teach a solid material that has been surface-treated while in a solid state with a dye to bind the dye or an oxidized cellulose having a covalently bond antioxidant dyestuff. Taken together these references do not provide any teaching, suggestion or motivation to arrive at the presently claimed invention and so would not have any expectation of success without the use of improper hindsight reasoning.

These arguments are unpersuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

As discussed in greater detail above, the claims as presented do not require covalent attachment of the antioxidant dyestuff to the bioabsorbable material. The references of Partain and Rosenthal are not deficient in regards to the independent claim, as discussed in greater detail above. Therefore, Gibbins is not required to cure these deficiencies. Applicants have not presented any arguments in regards to the teachings of Gibbins regarding the delivery vehicle being in the form of a sterile sheet or material and/or placing such material in a micro-organism impermeable container. Therefore, this rejection is maintained for the reasons of record.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW